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(54) Title: BIOLOGICAL REAGENTS AND METHODS TO VERIFY THE EFFICIENCY OF SAMPLE PREPARATION AND NUCLEIC ACID AMPLIFICATION AND/OR DETECTION

(57) Abstract: This invention relates to reagent comprising: any one of cells, viral particles, organelles, parasites, cells comprising organelles, cells comprising viral particles, cells comprising parasites, cells comprising bacterial cells and any combination thereof, the cells, viral particles, organelles or parasites comprising at least one nucleic acid sequence serving as an internal control (IC) target for nucleic acid testing (NAT) assay; wherein the reagent is suitable to be added to a test sample undergoing sample preparation to release, concentrate and/or purify nucleic acids and amplification and/or detection of nucleic acids so as to be used to verify: (i) the efficiency of sample preparation; and (ii) the efficiency of nucleic acid amplification and/or detection. The present invention also relates to a method to verify or validate the preparation and amplification and/or detection of a nucleic acid target sequence in a sample spiked with a reagent of the present invention.

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# INTERNATIONAL SEARCH REPORT

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## A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 C12Q1/68

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)  
IPC 7 C12Q

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the International search (name of data base and, where practical, search terms used)

EPO-Internal, BIOSIS, WPI Data, PAJ, EMBASE, CHEM ABS Data

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 02/18635 A (JONES ELIZABETH LOUISE ; BERG EINAR SVERRE (NO); STATENS INST FOR FOLK) 7 March 2002 (2002-03-07) pages 5-7, line 3 page 18, lines 27-35 page 19, line 20 - page 20, line 22 page 29, line 34 - page 30, line 12 page 33, line 31 - page 34, line 21 ----- -/--	1-4, 6-19, 23-32
Y		20-22

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

### \* Special categories of cited documents :

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- \*Y\* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
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## C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	KUSKE C R ET AL: "Small-scale DNA sample preparation method for field PCR detection of microbial cells and spores in soil" APPLIED AND ENVIRONMENTAL MICROBIOLOGY, WASHINGTON,DC, US, vol. 64, no. 7, July 1998 (1998-07), pages 2463-2472, XP002226433 ISSN: 0099-2240	1-5,9-14
Y	page 2464, left-hand column page 2465, right-hand column page 2471, right-hand column; table 1	20-22
X	WO 99/06594 A (MAINE MEDICAL CENTER) 11 February 1999 (1999-02-11)  page 4, lines 9-15 page 5, lines 1-13 page 6, line 19 - page 7, line 8	1-4, 7-19, 23-32
X	DATABASE BIOSIS 'Online! BIOSCIENCES INFORMATION SERVICE, PHILADELPHIA, PA, US; November 2002 (2002-11), LEBLANC E ET AL: "Less than one hour detection of Bacillus anthracis spores and vegetative cells from clinical specimens by fluorescence-based PCR" XP002283645 Database accession no. PREV200200585306 abstract & ABSTRACTS OF THE GENERAL MEETING OF THE AMERICAN SOCIETY FOR MICROBIOLOGY, vol. 102, May 2002 (2002-05), page 146, 102ND GENERAL MEETING OF THE AMERICAN SOCIETY FOR MICROBIOLOGY; SALT LAKE CITY, UT, USA; MAY 19-23, 2002 ISSN: 1060-2011	1-4,7-14
X	DATABASE BIOSIS 'Online! BIOSCIENCES INFORMATION SERVICE, PHILADELPHIA, PA, US; 2001, TREPANIER H ET AL: "One-hour detection of Candida albicans and Candida dubliniensis in blood samples using the Smart Cycler(R)" XP002283646 Database accession no. PREV200200201306 abstract & ABSTRACTS OF THE GENERAL MEETING OF THE AMERICAN SOCIETY FOR MICROBIOLOGY, vol. 101, 2001, page 241, 101ST GENERAL MEETING OF THE AMERICAN SOCIETY FOR MICROBIOLOGY; ORLANDO, FL, USA; MAY 20-24, 2001 ISSN: 1060-2011	1,2,9-14

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## C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	<p>BELANGER SIMON D ET AL: "Rapid detection of Shiga toxin-producing bacteria in feces by multiplex PCR with molecular beacons on the smart cycler"</p> <p>JOURNAL OF CLINICAL MICROBIOLOGY, WASHINGTON, DC, US, vol. 40, no. 4, April 2002 (2002-04), pages 1436-1440, XP002261197 ISSN: 0095-1137 page 1437, left-hand column</p> <p>-----</p>	1-3,9-14
A	<p>COURTNEY B C ET AL: "Development of internal controls for probe-based nucleic acid diagnostic assays."</p> <p>ANALYTICAL BIOCHEMISTRY. 1 JUN 1999, vol. 270, no. 2, 1 June 1999 (1999-06-01), pages 249-256, XP002283641 ISSN: 0003-2697 page 255, right-hand column - page 256, left-hand column</p> <p>-----</p>	1-32

# INTERNATIONAL SEARCH REPORT

Information on patent family members

Internat Application No  
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Patent document cited in search report		Publication date	Patent family member(s)	Publication date
WO 0218635	A	07-03-2002	AU 8420301 A	13-03-2002
			CA 2420845 A1	07-03-2002
			EP 1320631 A2	25-06-2003
			WO 0218635 A2	07-03-2002
			NO 20030917 A	16-04-2003
			US 2004101869 A1	27-05-2004
WO 9906594	A	11-02-1999	US 6074825 A	13-06-2000
			US 5994078 A	30-11-1999
			AU 8597598 A	22-02-1999
			WO 9906594 A1	11-02-1999